

THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT SEATTLE

UNITED STATES OF AMERICA,  
  
Plaintiff,  
  
v.  
  
PHYSIO-CONTROL, INC., a corporation,  
  
Defendant.

CASE NO. C08-0649-JCC  
  
ORDER

This matter comes before the Court on Defendant Physio-Control, Inc.’s (“Physio-Control”) unopposed motion to dissolve the consent decree (Dkt. No. 24) and supplemental brief in support (Dkt. No. 27). Having thoroughly considered the motion, supplemental brief, and relevant record, the Court hereby GRANTS the motion for the reasons explained herein.

In May 2008, the Court entered a consent decree permanently enjoining Defendants Medtronic, Inc., Physio-Control, William A. Hawkins, and Brian D. Webster from manufacturing or distributing Physio-Control External Defibrillators until Physio-Control could demonstrate compliance with the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351(h); 21 C.F.R. Part 820; and the Consent Decree. (Dkt. No. 3 at 3.) Among other things, the Consent decree required Physio-Control to make extensive changes to its quality system and mandated that those changes be evaluated and certified by an independent third party and subsequent inspections by Food and Drug Administration (FDA) personnel. (*Id.* at 3–6.) The consent decree

1 has been amended several times (Dkt. Nos. 6, 8, 10, 12, 14, 19, 22), and Physio-Control is the  
2 only remaining defendant.

3 Since the entry of the decree, Physio-Control has complied with its obligations and  
4 submitted all necessary reports to the FDA. (Dkt. No. 27 at 3–7.) In addition, Physio-Control has  
5 undergone two changes in ownership. (*Id.* at 2, 9.) Stryker Corporation has owned Physio-  
6 Control since April 2016, Physio-Control’s top management has been replaced, and Physio-  
7 Control has integrated into Stryker’s quality systems. (*Id.* at 9.) Finally, the FDA’s 2015 final  
8 order requiring a premarket approval application for all automated external defibrillators gives  
9 the FDA continued oversight of Physio-Control and its core line of medical products  
10 independent of the consent decree. *See Effective Date of Requirement for Premarket Approval*  
11 *for Automated External Defibrillator Systems*, 80 Fed. Reg. 4783 (Jan. 29, 2015).

12 The Court therefore FINDS that the purposes of the consent decree have been fully  
13 achieved and, due to changed factual and legal conditions, it is no longer necessary or equitable  
14 to keep the consent decree in effect. *See* Fed. R. Civ. P. 60(b)(5); *Rufo v. Inmates of Suffolk Cnty.*  
15 *Jail*, 502 U.S. 367, 383–85 (1992). The Court GRANTS Physio-Control’s motion (Dkt. No. 24),  
16 ORDERS that the consent decree as subsequently amended by orders of this Court (Dkt. Nos. 3,  
17 6, 8, 10, 12, 14, 19, 22) is VACATED and DISSOLVED in its entirety and shall be of no further  
18 effect, and DISMISSES this action with prejudice.

19 DATED this 29th day of March 2021.

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John C. Coughenour  
UNITED STATES DISTRICT JUDGE